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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,435	06/28/2004	Tatsuo Kamata	10873.1416USWO	7700
52835	7590	10/27/2006	EXAMINER	
HAMRE, SCHUMANN, MUELLER & LARSON, P.C. P.O. BOX 2902 MINNEAPOLIS, MN 55402-0902			BABIC, CHRISTOPHER M	
			ART UNIT	PAPER NUMBER
			1637	
DATE MAILED: 10/27/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/500,435	Applicant(s) KAMATA ET AL.	
	Examiner Christopher M. Babic	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 8-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 8-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/2/2006</u> <u>7-27-06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

Claims 1-6 and 8-13 are pending. The following Office Action is in response to Applicant's response dated August 8, 2006.

Claim Rejections - 35 USC § 102

The rejections of claim(s) 1-3, 5-7, and 11-13 over Robson have been withdrawn in view of Applicant's amendment.

The rejections of claim(s) 1-3, 5, 6, and 8-13 over Britschgi have been withdrawn in view of Applicant's amendment.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following new ground(s) of rejection was necessitated by Applicant's amendment.

1. Claims 1-3, 5, 6, and 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Pierre et al. ("Use of a reamplification protocol

improves sensitivity of detection of Mycobacterium tuberculosis in clinical samples by amplification of DNA" J Clin Microbiol. 1991 Apr;29(4):712-7).

With regard to claim 1, it is initially noted that the term "containing" can be interpreted as "open" language. Thus, the liquid may contain any number of components in addition to the specific non-ionic surfactant.

Pierre et al. teach a method comprising: heating the acid-fast bacterium (page 713, col. 1, extraction, for example) in a liquid containing a non-ionic detergent (page 713, col. 1, extraction, Tween-20/Triton X-100, for example) at a temperature below a boiling point of the liquid (page 713, col. 1, extraction, 95°C, for example), *wherein the non-ionic surfactant detergent is selected from polyoxyethyleneglycol p-t-octylphenyl ethers* (page 713, col. 1, extraction, Triton X-100, for example). Thus, claim 1 as amended is anticipated by the teachings of Pierre.

With regard to claim 2, Pierre teaches a heating temperature not less than 70°C and less than 100°C (page 713, col. 1, extraction, 95°C, for example).

With regard to claim 3, Pierre teaches heating performed for 1 to 30 minutes (page 713, col. 1, extraction, 10 min., for example).

With regard to claim 5, Pierre teaches a pH of the liquid is in a range from 7.0 to 12.0 (page 713, col. 1, amplification, 8.3, for example).

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With regard to claim 6, Pierre teaches a concentration of the non-ionic detergent in the liquid is 0.01 to 10 wt% (page 713, col. 1, extraction, 0.45% Triton X-100, for example).

With regard to claim 11, Pierre teaches *M. tuberculosis* (page 713, col. 1, for example).

With regard to claim 12, Pierre teaches acid-fast bacterium selected from tissue (page 713, col. 1, for example).

With regard to claim 13, Pierre the subsequent amplification of a gene extracted from a sample (page 713, col. 1, amplification, 8.3, for example).

The following new ground(s) of rejection was necessitated by the IDS filed August 8, 2006.

2. Claims 1, 5, 6, and 8-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Sritharan et al. ("A simple method for diagnosing M. tuberculosis infection in clinical samples using PCR" Mol Cell Probes. 1991 Oct;5(5):385-95).

With regard to claim 1, it is initially noted that the heating step can be interpreted to encompass any time during the entire heating process.

Sritharan et al. teach a method comprising: heating the acid-fast bacterium (page 387, col. 2, method 1, for example) in a liquid containing a non-ionic detergent (page 387, col. 2, method 1, Triton X-100, for example) at a

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temperature below a boiling point of the liquid (page 387, col. 2, method 1, e.g. the heating *before* boiling, for example), *wherein the non-ionic surfactant detergent is selected from polyoxyethyleneglycol p-t-octylphenyl ethers* (page 387, col. 2, method 1, Triton X-100, for example). Thus, claim 1 as amended is anticipated by the teachings of Sritharan.

With regard to claim 5, Sritharan teaches a pH of the liquid is in a range from 7.0 to 12.0 (page 387, col. 2, method 1, 8.0, for example).

With regard to claim 6, Sritharan teaches a concentration of the non-ionic detergent in the liquid is 0.01 to 10 wt% (page 387, col. 2, method 1, 1% Triton X-100, for example).

With regard to claims 8-10, Sritharan teaches 1 mM EDTA (page 387, col. 2, method 1, for example).

With regard to claim 11, Sritharan teaches *M. tuberculosis* (page 387, col. 2, for example).

With regard to claim 12, Sritharan teaches acid-fast bacterium selected from tissue (page 387, col. 2, for example).

With regard to claim 13, Sritharan the subsequent amplification of a gene extracted from a sample (page 387, col. 1, for example).

Claim Rejections - 35 USC § 103

The rejections of claim(s) 4 and 7 over Britschgi in view of Pierre have been withdrawn in view of Applicant's amendment.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The following new ground(s) of rejection was necessitated by Applicant's amendment.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pierre et al. ("Use of a reamplification protocol improves sensitivity of detection of Mycobacterium tuberculosis in clinical samples by amplification of DNA" J Clin Microbiol. 1991 Apr;29(4):712-7).

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With regard to claim 4, Pierre expressly teaches the successful extraction of DNA from mycobacterium including heating the sample in a non-ionic detergent at 95°C for 10 minutes.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to optimize the heating temperatures and times. An ordinary practitioner would have recognized that the optimizable variables of heating temperature and time could be adjusted to maximize the desired results. As noted in *In re Aller*, 105 USPQ 233 at 235,

More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.

Routine optimization is not considered inventive and no evidence has been presented that the selection of specific times or temperatures was other than routine or that the results should be considered unexpected in any way as compared to the closest prior art.

Response to Declaration under 37 CFR 1.132

The evidence of unexpected results presented by Yuji Izumizawa under 37 CFR 1.132 filed August 8, 2006 is moot because the rejections of claim(s) 4 and 7 over Britschgi in view of Pierre have been withdrawn in view of Applicant's amendment. Claim 1 remains anticipated by the teachings of Pierre and Sritharan, respectively.

However, it is submitted that the evidence presented would not have been sufficient to overcome the rejection because, based on the evidence presented, most specifically the electrophoresis figure on page 3, a practitioner of ordinary skill in the art would not be able to conclude that the TE-Triton method produced a stronger band than the TE-Tween 20 method. The figure presented is of low quality and in no way provides a clear and concise result. Thus, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

Conclusion

Claims 1-6 and 8-13 are rejected. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Furthermore, Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on August 8, 2006 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b) as well as MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory

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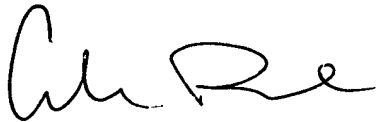
action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Babic whose telephone number is 571-272-8507. The examiner can normally be reached on Monday-Friday 7:00AM to 4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

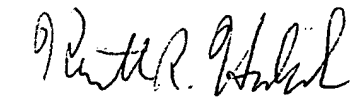
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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



10/13/06

Christopher M. Babic
Patent Examiner
AU 1637



KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

10/16/06